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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/810,258 | 03/26/2004 | Qianjin Hu | 433112001000 | 8314 |
| 25226 | 7590 | 03/06/2006 | EXAMINER | |
| MORRISON & FOERSTER LLP | | | HINES, JANA A | |
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| PALO ALTO, CA 94304-1018 | | | 1645 | |

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/810,258 | HU ET AL. | |
| | Examiner Ja-Na Hines | Art Unit 1645 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 November 2005.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-31 is/are pending in the application.
 4a) Of the above claim(s) 26-28 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-25 and 29-31 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>3/3/05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in the reply filed on November 17, 2005 is acknowledged. Claims 26-28 have been withdrawn from consideration. Claims 1-25 and 29-31 are under consideration in this office action.

Specification

2. The use of the trademark TEFLON™ and other product names have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 16, and 21-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) The claim scope of claim 16 is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or

trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a particular material, i.e. TEFLON™ and accordingly, the identification is indefinite. Furthermore, the use of trademarks is improper since products identified by trademarks are within the sole control of the trademark owner and are subject to change by said owner at their discretion.

- b) Claim 21 recites the limitation "the average distance" in the claim. There is insufficient antecedent basis for this limitation in the claim. Thus, clarification is required to overcome the rejection.
- c) Claim 24 recites the limitation "the volume" in the claim. There is insufficient antecedent basis for this limitation in the claim. Thus, clarification is required to overcome the rejection.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-25 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Juncosa et al., (US Patent 6,255,109).

The claims are drawn to a multi-array system, comprising: a first solid substrate having a first surface; a second solid substrate having a second surface, wherein the first and second solid substrates are positioned so that the first surface faces the second surface; a spacer contacting and separating the first and second solid substrates, so as to form at least one reaction chamber comprising a fluid-receiving space between the first and second surfaces, a first biomolecule array immobilized on the first surface; and a second biomolecule array immobilized on the second surface, wherein the first and second biomolecule arrays are exposed to the fluid-receiving space. The dependant claims are drawn to the reaction chambers, the openings, and the formation and materials of the first and second substrates and the spacer.

Juncosa et al., teach a genetic analysis device. The device includes a pair of glass slide members and an elastomer middle layer and members to hold the device together (col. 6, lines 7-10). Thus the pair of glass slides are equivalent to the first and second solid supports, each having a surface, just as required by the claims. The middle layer is equivalent to the spacer. The body of the device of a U-shaped housing member, and positioned within the housing is a middle layer, two slide members and two biasing members (col. 6, lines 10-17). Thus the first and second glass supports are substantially enclosed in substantially parallel plane positions such that the first surface

faces the second surface to create a reaction chamber, based on the U shaped configuration, thereby meeting the limitations of the claims. The middle layer is preferably made of a moldable elastomer such as liquid silicone rubber (LSR) or equivalent material (col. 6, lines 18-20). Thus the spacer or middle layer is made of the same instantly recited rubber or silicone rubber materials. The cavities or reaction chambers in the middle layer are designed to be very small and micro-sized (col. 2, lines 39-41). Thus, the average distances between the first and second substrates are simply optimization procedures and these inherent changes in distances between the first and second substrates are not held to be patentable.

The elastomer material also conforms to the glass slides and creates a liquid tight seal against them (col. 6, lines 20-23). Therefore the spacer forms a watertight seal with the first and second supports, just as required by the claims. However the adherence of such material to the glass is also reversible (col. 5 lines 1-5). Thus, the spacer is removable adhered to the first and second surfaces, just as a required by the claims. The slide members are made of glass and each of the slide members contains areas or sites that comprises arrays of deposited oligonucleotides (col. 6, lines 37-43). Thus, the arrays can be a polynucleotide or oligonucleotide arrays just as instantly required. Moreover, the art teaches that the glass slides come imprinted, therefore any type of array can be imprinted and no more then routine skill is required to purchase imprinted glass slides. Thus, the first and second substrates, comprising the same or different biomolecules are known in the art. The glass can be silanized after the arrays are printed and immobilized on it for further coating (col. 5, lines 1-5). Thus the first and

second substrates are coated glass slides. Rather than have opening in the middle layer, a plurality of openings can be providing the housing member to provide access and allow the liquid to exit from the device (col. 7, lines 4-15). Seals between the assay devices and the support base along with the closed fluidic system within the support base prevents the sample from prematurely entering the cavities of the device (col. 8, lines 1-5). Thus there are one or more sealable opening, just as required by the claims.

5. Claims 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Juncosa et al., (US Patent 6,255,109).

The claims are drawn to a method of making a multi-array system, comprising the steps of: providing a first substrate having a first surface, wherein a first biomolecule array is immobilized on the first surface; providing a second solid substrate having a second surface, wherein a second biomolecule array is immobilized on the second surface; and fixably positioning the first and second solid substrates using a spacer so as to form a reaction chamber in which the first and second surfaces face each other and are separated by a fluid-receiving space, and in which the first and second biomolecule arrays are exposed to the fluid-receiving space. The dependent claims are drawn to a kit comprising the multi-array system and instructions regarding the use of the multi-array system.

Juncosa et al., teach a fluid sampling device with separate components which can be assembled and dissembled (col. 1-2, lines 65-3). The device includes a pair of glass slide members and an elastomer middle layer and members to hold the device

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together (col. 6, lines 7-10). The glass comprises printed and immobilized oligonucleotide or DNA containing arrays on it (col. 5, lines 1-5). Thus the art clearly teaches a method of making the multi-array system by providing a first and second substrate wherein the biomolecule arrays is imprinted and immobilized on the glass slide. The art teaches an improved assay and analytical devise, process and system along with how to use the device with standard laboratory equipment (col. 11, lines 34-40). Thus, Juncosa et al., teach the kit, since the instantly claimed kit only comprises the device and instructions.

Prior Art

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ribi (US Patent 5,622,872) Ribi depicts Figure 3 which shows two substrates facing each other wherein each substrate has immobilized thereon specific binding members for binding receptors and a sealant layer.

Conclusion

7. No claims allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines 
February 15, 2006

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